§ 520.804 Enalapril tablets.

(a) *Specifications*. Each tablet contains either 1.0, 2.5, 5.0, 10.0, or 20.0 milligrams of enalapril maleate.

(b) *Sponsor*. See 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 0.5 to 1.0 milligram of enalapril maleate per kilogram of body weight per day.

(ii) *Indications for use*. Treatment of mild, moderate, and severe (modified New York Heart Association Class II, III, IV) heart failure in dogs.

(iii) *Limitations*. Use 0.5 milligram per kilogram once daily. In the absence of adequate clinical response within a 2-week period, use may be increased to twice daily (a total of 1.0 milligram per kilogram). Enalapril maleate is administered as conjunctive therapy with furosemide and digoxin in the treatment of dilated cardiomyopathy and furosemide with or without digoxin in the treatment of chronic valvular disease. The safety of enalapril for use in breeding dogs has not been established. Use in pregnant bitches is not recommended. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[59 FR 17694, Apr. 14, 1994, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.812 Enrofloxacin tablets.

(a) *Specifications*. Each tablet contains either 22.7, 68.0, or 136.0 milligrams of enrofloxacin.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount*. 5 to 20 milligrams per kilogram (2.27 to 9.07 milligrams per pound) of body weight.

(2) *Indications for use*. Dogs and cats for management of diseases associated with bacteria susceptible to enrofloxacin.

(3) *Limitations*. Administer orally as a single dose or divided into 2 equal doses at 12 hour intervals, daily. Administer for at least 2 to 3 days beyond cessation of clinical symptoms, for a maximum of 30 days. Safety in breeding or pregnant cats has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 3444, Jan. 24, 1989, as amended at 55 FR 43327, Oct. 29, 1990; 62 FR 38906, July 21, 1997; 64 FR 48295, Sept. 3, 1999]

§ 520.813 Enrofloxacin oral solution.

(a) *Specifications*. Each milliliter of concentrate solution contains 32.3 milligrams of enrofloxacin.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.228 of this chapter.

(d) *Conditions of use*. It is used in drinking water as follows:

(1) *Chickens and turkeys*—(i) *Amount*. 25 to 50 parts per million of enrofloxacin in drinking water.

(ii) *Indications*. Chickens: Control of mortality associated with *Escherichia coli* susceptible to enrofloxacin. Turkeys: Control of mortality associated with *E. coli* and *Pasteurella multocida* (fowl cholera) susceptible to enrofloxacin.

(iii) *Limitations*. Do not use in laying hens producing eggs for human consumption. Administer medicated water continuously as sole source of drinking water for 3 to 7 days. Prepare fresh stock solution daily. Effects on the reproductive function of turkeys have not been determined. Treated animals must not be slaughtered for food within 2 days of the last treatment. Individuals with a history of hypersensitivity to quinolones should avoid exposure to this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[61 FR 56893, Nov. 5, 1996]

§ 520.816 Epsiprantel tablets.

(a) *Specifications*. Each tablet contains either 12.5, 25, 50, or 100 milligrams of epsiprantel.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 2.5 milligrams per pound of body weight.

(ii) *Indications for use*. Removal of canine cestodes *Dipylidium caninum* and *Taenia pisiformis*.

(2) *Cats*—(i) *Amount*. 1.25 milligrams per pound of body weight.

(ii) *Indications for use.* Removal of feline cestodes *D. caninum* and *T. taeniaeformis.*

(3) *Limitations.* For oral use only as a single dose. Do not use in animals less than 7 weeks of age. Safety of use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 50615, Dec. 8, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.823 Erythromycin phosphate.

(a) *Specifications.* Erythromycin phosphate is the phosphate salt of the antibiotic substance produced by the growth of *Streptomyces erythreus* or the same antibiotic substance produced by any other means. One gram of erythromycin phosphate is equivalent to 0.89 gram of erythromycin master standard.

(b) *Sponsor.* See No. 061133 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.230 of this chapter.

(d) *Conditions of use.* It is used in drinking water as follows:

(1) *Broiler and replacement chickens*—(i) *Amount.* 0.500 gram per gallon.

(ii) *Indications for use.* As an aid in the control of chronic respiratory disease due to *Mycoplasma gallisepticum* susceptible to erythromycin.

(iii) *Limitations.* Administer for 5 days; do not use in replacement pullets over 16 weeks of age; do not use in chickens producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

(2) *Replacement chickens and chicken breeders*—(i) *Amount.* 0.500 gram per gallon.

(ii) *Indications for use.* As an aid in the control of infectious coryza due to *Hemophilus gallinarum* susceptible to erythromycin.

(iii) *Limitations.* Administer for 7 days; do not use in replacement pullets over 16 weeks of age; do not use in chickens producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

(3) *Growing turkeys*—(i) *Amount.* 0.500 gram per gallon.

(ii) *Indications for use.* As an aid in the control of blue comb (nonspecific infectious enteritis) caused by organisms susceptible to erythromycin.

(iii) *Limitations.* Administer for 7 days; do not use in turkeys producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 56798, Aug. 26, 1980; 66 FR 14073, Mar. 9, 2001]

§ 520.863 Ethylisobutrazine hydrochloride tablets.

(a) *Specifications.* Each tablet contains either 10 milligrams or 50 milligrams of ethylisobutrazine hydrochloride.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is administered orally to dogs as a tranquilizer.[1]

(2) It is administered once daily at a dosage level of 2 to 5 milligrams of ethylisobutrazine hydrochloride per pound of body weight.[1]

(3) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride because phenothiazine may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.[1]

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.